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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,428	10/30/2003	George Verlaan	05032-00043	7731

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EXAMINER
KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,428	VERLAAN ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2006 and 19 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-55,61-76,85,86 and 90-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-55,61-76,85,86 and 90-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114.

2. By Amendment filed December 18, 2006, Claim 46 has been amended.

3. Claims 46-55, 61-76, 85-86 and 90-92 are currently pending for prosecution of the merits of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 46-55, 62-71, 73-76, 85-86 and 90-92 are rejected under 35 USC 103(a) as being unpatentable over Simone (US 5397786) in view of Thomas et al. (US 5972985), Buchholz et al. (US 6514973) and Hageman et al. (US 6420342 B1).

The claims read on fluid composition comprising at least one of methyl amine selected from dimethylglycine and sarcosine in the amount of 0.2-10g/l, one or more digestible carbohydrates in the amounts of 20-75 g/l, and one or more minerals selected from calcium and magnesium, wherein said fluid has an essentially hypotonic osmolarity in the range of 70 to 275 mgOsm/l.

Simone teaches a hypotonic rehydration or nutritional drink, comprises 1 to 30mg of betaine, methionine and/or choline, 1 to 100g of carbohydrates in the form of monosaccharides, oligosaccharides and/or polysaccharides (e.g., glucose, glucose polymers, ribose, mannose, fructose, galactose, maltodextrin, maltose, etc...), 2 to 2500mg of minerals (e.g., magnesium, calcium, sodium, potassium, etc...), vitamins (e.g., vitamin C, vitamin E, etc...), wherein said composition is useful for treating dehydration symptoms due to exposure to high temperature and/or heavy physical exercise, severe diarrhea or vomiting for a variety of causes such as gastrointerstinal disorders, cardiovascular disorders, and chronic illnesses such as cancer (column 2, line 45 thru column 4, line 22; Table 1; column 5, lines 37-55; Claims 13-14 and 17-18).

Thomas teaches a rehydration or nutritional solution comprising histidine, vitamins (i.e., vitamin C, ascorbate, vitamin E, beta-carotene, vitamin A), glycerol, minerals (i.e., copper, iron, magnesium, manganese, zinc, iron, selenium) and lipoic acid (abstract; column 7, line 25; column 9, line 60 thru column 11, line 22; column 11, lines 33-35).

Buchholz teaches sarcosine or dimethylglycine as functional equivalent to betaine as a methyl donor (column 3,lines 6-8; column 4, lines 62-65).

Hageman teaches a nutritional composition containing carbohydrates (e.g., ribose, maltodextrin), taurine, alpha-lipoic acid, folic acid, citrate or phosphate in the form of electrolytes (e.g., magnesium phosphate and zinc citrate), vitamins (e.g., B1, B6 and B12), betaine, choline, protein and histidine that is useful for trauma, surgery, cancer, rehydration, cardiovascular or cerebrovascular disorder (Table 1; column 13, lines 22-35; claims).

The teaching of Simone differs from the claimed invention in (i) the use of other methyl amine such as dimethylglycine and sarcosine in said composition; (ii) the specific osmolarity of said composition, "in the range of 70 to 275 mOsm/l" (claim 46); (iii) the specific dry mass content of ingredients in said composition, "a dry mass content of 9 wt% or less" (claim 48); (iv) the specific amounts of active and inactive ingredients in a composition, "the amount of methyl amine being between 01.2-10 g/l" and "the digestible carbohydrate is in the amount of between 20-75 g/l" (claim 46), "the digestible carbohydrate concentration is between 10 and 80 g/l" (claim 49), "at least 0.5 g/l of the digestible carbohydrate is ribose or innositol" (claim 50), "fructose and mannose together are present in an amount between 0.05-06 mole per mole glucose" (claim 54), "one or more carbohydrates comprises at least 0.5 g/l ribose, at least 0.5 g/l inositol and/or at least 0.5 g/l galactose" (claim 55), "the mineral concentration is between 0.1 and 30 g/l" (claim 61), "the magnesium concentration if 100mg/l or more" (claim 63), "the zinc concentration is 10mg/l or more" (claim 64), "the calcium concentration is 300 mg/l or more" (claim 65), "the iron concentration is 5mg/l or more" (claim 66), "glycerol is present in a concentration of 0.1-20 g/l" (claim 67), "lipoic acid is present in a concentration of at least 20

mg/l" (claim 68), "taurine is present in a concnetraiton of 0.1-2 g/l and wherein citrate is present in a concentration of 0.2-2 g/l" (claim 71), "caffeine is present in a concentration of 0.1-1 g/l" (claim 72) and "a nitrogen content of less than 3 g/l" (claim 75); (v) the specific mixtures of carbohydrates in a composition; (vi) the specific pH of the claimed invention, "in the range of 2.5-6.8" (claim 74); and (vii) the incorporation of secondary ingredients such as zinc, iron, glycerol, lipoic acid, taurine and citrate in said composition.

However, it would have been obvious to a person skill in the art, at the time of the invention was made, to arrive at the claimed invention containing all the ingredients herein (a methyl amine (source of nitrogen), vitamins, carbohydrates, glycerol, minerals, lipoic acid, etc...). All the ingredients employed herein are known to be useful in preparing rehydration drink or solution. Furthermore, one having ordinary skill in the art would have expected that substitution of betaine with other known methyl donor such as dimethylglycine and sarcosine would provide similar activity of the compound of the reference due to their art-recognized equivalent functional property. Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

In addition, it would have been apparent to those skilled in the art to optimize amounts of known active and inactive ingredients in a composition; the specific pH of the final composition;

the dry mass of the ingredients in a composition; the specific mixtures of kwon digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose, inositol); and concurrent administration regimens as determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate dosage amounts for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed herein.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

With respect to "treating hypohydration", "treats hypohydration when administered to a subject in need thereof", "for treating an ill subject" and "the ill subject is subject suffering from hypohydration selected from the group consisting of a subject that used a drug having a diuretic action, a subject having a spinal cord injury, a subject in a coma, a subject who is confined to bed and a subject having a kidney dysfunction" in claims 46, 91 and 92 respectively, such statements of intended use or purpose are not limited to the interpretation of the composition claims since the patentability of the product is not dependent upon the manner in which the product is going to be ultimately used. Therefore, the references in combination make obvious the instant invention.

5. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simone (US 5397786) in view of Thomas et al. (US 5972985), Buchholz et al. (US 6514973) and Kampinga et al. (US 6455511 B1) and further in view of Kuznicki et al. (US 5464619). See above 35 USC 103(a) rejection.

The modified teaching of Simone includes all that is recited in claims 25 and 28 except the incorporation of caffeine into said composition.

Kuznicki teaches a rehydration composition containing electrolytes, carbohydrates or carbohydrate derivatives (e.g., fructose, glucose, maltodextrin, glycerol), caffeine and vitamins (abstract, column 4, lines 53-61; column 6, lines 37-44).

To incorporate such teaching into the teaching of Simone, would have been obvious in view of Kuznicki who teaches the use of caffeine in rehydation solution.

Above references in combination makes clear that the use of caffeine in rehydation solution is old and well known. Above references in combination makes clear that the formulation containing diemthyglycine, one or more digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose and inositol), minerals, caffeine, glycerol and vitamins are old and well known.

In addition, it would have been apparent to those skilled in the art to optimize amounts of known active and inactive ingredients in a composition. Determination of the appropriate dosage amounts for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed herein.

Response to Arguments

6. Applicant's arguments filed July 19, 2006 have been fully considered but they are not persuasive.

Applicant's argument takes the position that the cited references, alone or in combination, fail to teach or suggest each and every elements of Applicant's claimed composition, particularly (i) the benefit of using the instant composition for "treating hypohydration" and (ii) the specific osmolarity ("osmolarity of between 70 and 275 mOsm/l") and the use of "sarcosine or dimethylglycine" required by the instant claims.

This argument is not found persuasive. As discussed above as well as the previous O.A. mailed 10/16/2006, the statements of intended use or purpose are not limited the interpretation of the composition claim since the patentability of product is not dependent manner in which the product is going to be ultimately used. Therefore, the references in combination make obvious the instant invention.

In response to the applicant's argument that the applicant has surprisingly discovered that the instant composition provides unexpected results in treating hypohydration via (i) promoting the absorption of water by body, (ii) preventing bodily water perturbations, promoting homeostasis and rapidly restoring the water content of the body after dehydration, and (iii) protecting against the secondary effects of hypohydration without giving rise to undesired side effects, the examiner recognizes that the applicant's mere statement that the instant composition is capable of achieving the desired effects without supporting evidence is not sufficient to overcome the rejection of the record.

In response to the applicant's argument that there is no teaching or suggestion in using "osmolarity of between 70 and 275 mOsm/l", the examiner recognizes that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable concentration ranges by routine experimentation. Therefore, in absence of showing the superior unexpected results of the composition having the specific osmolarity over the prior art, the examiner maintains that the references in combination make obvious the instant invention.

In response to applicant's argument that there is no teaching or suggestion for the inclusion of sarcosine or dimethylglcyine, the examiner recognizes that sarcosine or dimethylglycine is art-recognized equivalents to betaine at the time of the invention was made (as evidenced by Buchholz, which is similarly noted by the applicant in the instant specification, page 9, lines 18-20). Thus, the examiner maintains that one of ordinary skill would have found it is obvious to substitute a sarcosine or dimethylglycine for betaine.

Relevant Art of Record

7. The art made of record and not relied upon is considered pertinent to applicant's invention. It is noted to applicant that USP 6514973, USP 5580856, USP 6020139, USP 5389383 and US PG Pub 20040192615 which have been cited in the inst PTO-892 disclose

betaine, sarcosine, choline and dimethylglycine as functional equivalents (as known methyl donor compounds or osmoprotectant compounds).

Conclusion

8. As indicated in above, this application is a RCE (Request for Continued Examination) filed under 37 CFR 1.1114. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
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